

**PCT**WORLD INTELLECTUAL PROPERTY ORGANIZATION  
International Bureau

## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : <b>A61K 33/14, A61M 1/16, 1/28 // (A61K 33/14, 33:10, 33:00, 31:70, 31:19)</b>		<b>A1</b>	(11) International Publication Number: <b>WO 96/01118</b>
			(43) International Publication Date: <b>18 January 1996 (18.01.96)</b>
(21) International Application Number: <b>PCT/US95/06784</b>			(81) Designated States: AU, BR, CA, CN, JP, MX, SG, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).  <b>Published</b> <i>With international search report.</i>
(22) International Filing Date: <b>25 May 1995 (25.05.95)</b>			
(30) Priority Data: 08/269,497      1 July 1994 (01.07.94)      US 08/421,020      12 April 1995 (12.04.95)      US			
(71) Applicant: <b>BAXTER INTERNATIONAL INC. [US/US]; One Baxter Parkway, Deerfield, IL 60015 (US).</b>			
(72) Inventors: <b>MARTIS, Loe; 5524 Oldwood, Long Grove, IL 60047 (US). HENDERSON, Lee, W.; 725 North Sheridan Road, Lake Forest, IL 60045 (US).</b>			
(74) Agents: <b>BORECKI, Thomas, S. et al.; 1620 North Waukegan Road, McGaw Park, IL 60085 (US).</b>			
(54) Title: <b>BIOCHEMICALLY BALANCED PERITONEAL DIALYSIS SOLUTIONS</b>			
(57) Abstract <p>A peritoneal dialysis solution that is biochemically balanced to correct metabolic acidosis associated with chronic renal failure in a more physiological manner. The peritoneal dialysis solution has a physiological pH, e.g., pH of 7.0 to 7.4, and contains bicarbonate at a concentration that is found in normal blood. Additionally, the solution contains carbon dioxide at a partial pressure that is similar to partial pressure of carbon dioxide found in normal blood. The peritoneal dialysis solution also contains a weak acid with a pKa of less than 5.0.</p>			

- 13 -

WE CLAIM:

1. A peritoneal dialysis solution including bicarbonate at a level of greater than or equal to 20 mM/L and less than or equal to 30 mM/L, having a carbon dioxide partial pressure that is less than 60 mmHg and including at least one weak acid present in an amount comprising approximately 10 mEq/L to about 20 mEq/L selected from the group consisting of: lactate; pyruvate; citrate; isocitrate; cis-aconitase;  $\alpha$ -ketoglutarate; succinate; fumarate; malate; and oxaloacetate.

2. The peritoneal dialysis solution of Claim 1 wherein bicarbonate is present in the solution at 25 mM/L.

3. The peritoneal dialysis solution of Claim 1 wherein the carbon dioxide partial pressure of the solution is approximately the same as the carbon dioxide partial pressure of blood.

4. The peritoneal dialysis solution of Claim 1 wherein the solution has a pH of approximately 7.0 to about 7.4.

5. The peritoneal dialysis solution of Claim 1 wherein the weak acids have a pKa of < 5.0.

6. The peritoneal dialysis solution of Claim 1 wherein the carbon dioxide partial pressure of the solution is approximately the same as the carbon dioxide partial pressure of blood.

7. A peritoneal dialysis solution comprising:

Dextrose (hydrous) (g/dl)	1.5-4.25
Sodium (mEq/L)	100-140
Chloride (mEq/L)	70-110
Calcium (mEq/L)	0.0-4.0
Magnesium (mEq/L)	0.0-4.0

- 14 -

Bicarbonate (mEq/L)	20.0-30.0
Weak acid (mEq/L)	10.0-20.0

wherein the weak acid is at least one acid chosen from the group consisting of: lactate; pyruvate; citrate; isocitrate; cis-aconitase;  $\alpha$ -ketoglutarate; succinate; fumarate; malate; and oxaloacetate.

8. The peritoneal dialysis solution of Claim 7 wherein the solution has a pH of approximately 7.0 to about 7.4.

9. The peritoneal dialysis solution of Claim 7 wherein the weak acids have a pKa of < 5.0.

10. The peritoneal dialysis solution of Claim 7 wherein the carbon dioxide partial pressure is less than 60 mmHg.

11. The peritoneal dialysis solution of Claim 7 wherein the carbon dioxide partial pressure of the solution is approximately the same as the carbon dioxide partial pressure of normal blood.

12. A peritoneal dialysis solution comprising:

Dextrose (hydrous) (g/dl)	1.5-4.25
Sodium (mEq/L)	100-140
Chloride (mEq/L)	70-110
Calcium (mEq/L)	0.0-4.0
Magnesium (mEq/L)	0.0-4.0
Bicarbonate (mEq/L)	20.0-30.0
Weak acid (mEq/L)	10.0-20.0

wherein the weak acid is at least one acid chosen from the group consisting of: lactate; pyruvate; citrate; isocitrate; cis-aconitase;  $\alpha$ -ketoglutarate; succinate; fumarate; malate; and oxaloacetate; and

the solution has a carbon dioxide partial pressure that is substantially similar to the carbon dioxide

- 15 -

partial pressure of a normal subject's blood and the solution has a pH of 7.0 to 7.4.

13. A method for correcting metabolic acidosis in a dialysis patient suffering or likely to suffer from same comprising the step of:

administering to a patient a peritoneal dialysis solution that has a bicarbonate level and carbon dioxide partial pressure that are substantially similar to that found in the patient's blood.

14. The method of Claim 13 wherein the solution comprises:

	Dextrose (hydrous) (g/dl)	1.5-4.25
	Sodium (mEq/L)	100-140
	Chloride (mEq/L)	70-110
15	Calcium (mEq/L)	0.0-4.0
	Magnesium (mEq/L)	0.0-4.0
	Bicarbonate (mEq/L)	20.0-30.0
	Weak acid (mEq/L)	10.0-20.0

15. The method of Claim 13 including the step of administering to the patient a weak acid that is present in the solution in an amount that offsets the daily hydrogen production of approximately 1 mEq/kg/day.

16. The method of Claim 15 wherein the weak acids have a pKa of < 5.0.

17. The method of Claim 14 wherein the solution has a pH of approximately 7.0 to about 7.4.

18. The method of Claim 13 wherein the solution does not include lactate.

19. The method of Claim 15 wherein the weak acid is present in the solution at a level of approximately 10 to about 20 mEq/L.